

Funding of Validation of Test Methods from the Small Business Perspective

Presented by:

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Development of Test Methods has little market potential for conventional forms of funding:

- o Large pharmaceutical companies (Big Pharma) require a considerable market potential before expending funds to develop drugs targeted for disease areas.
- o Venture capital also requires a considerable market potential before expending funds.
- o Development of Test Methods for Public Health purposes has an unknown market potential.
- o Government is an appropriate source for funding development and validation of testing methods to protect the public health.

Government is the Primary Source to Fund Areas of Research for Public Health:

- Test Method Development and Validation is a major program area of the National Toxicology Program (NTP), Interagency Coordinating Council for the Validation of Alternative Methods (ICCVAM), and NICEATM.
- The Annual Plan for fiscal year 2002: The National Toxicology Program has a total budget of 145.2 Million dollars
 - 106.9 Million dollars for Toxicity Studies
 - 31.4 Million dollars for Methods Development

Government is the Primary Source to Fund Areas of Research for Public Health: (continued)

- o NIEHS SBIR Program has a budget of approximately 10 Million dollars for Phase I and Phase II Programs. Adding a Phase III Program would require input of more funds
- o US EPA had a budget of 30.5 Million dollars for Endocrine Disruptor Development and Validation. All of these funds have been contracted to the Battelle Corporation and no funds are available for small business validation studies of other technology that is developed.
- o Other Sources?

Small Business Initiated Research Program:

- o A funding mechanism does exist for Small Business Entities (companies) to propose Test Methods and develop the test methods. This is through the Small Business Initiated Research (SBIR) Program.
- o The SBIR funding mechanism currently has a Phase I component (proof of concept) and a Phase II component (development of product).

A phase III SBIR process of proposal of research at NIH and peer review to take methods thru a validation phase does not exist but has been proposed.

Small Business Initiated Research Program: (continued)

- o Therefore, there is no process for XDS to propose validation of the methodology we have developed to meet NTP program initiatives to be funded and to receive external peer review.
- o The methodology that has been developed limits or eliminates the use of animals in determining the effects of exposure to chemicals and their effects on Public Health. A major program initiative of ICCVAM.

Proposal from the Small Business Perspective on the Funding Process:

- The SBIR Phase I and Phase II components are appropriate mechanisms for companies to develop products to meet government needs since they incorporate a mechanism for proposal of research and a rigorous peer review process.**
- This committee SACATM should act as the peer review process to bring methods to validation by ICCVAM and NICEATM. If a method has been through this process, it has already been subjected to two exhaustive peer review process evaluations and should be ready for validation by ICCVAM and NICEATM.**

A recommendation of a standardized process for proposal and review of submissions to ICCVAM is a mandate for SACATM.